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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
STULII, VERA	

ART UNIT	PAPER NUMBER
1781	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/520,004	MAYE ET AL.	
	Examiner	Art Unit	
	VERA STULII	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The prosecution on this case has been reopened by the Panel decision from the Pre-Appeal Brief Review (see Pre-Brief Appeal Conference decision mailed 01/11/2010).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

i) Claims 2-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41 and 43-47of copending Application No. 11/473,533.

ii) Claims 2-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-40 of copending Application No. 10/361976.

iii) Claims 2-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/545326.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the addition of various types of hops acid solutions to fermentation media, including brewing and production of alcohol spirits, in order to avoid contamination by undesired microorganisms. Further, the recited method steps do not add patentable distinction between the two.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-6, 8-11, 14-15 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of ALCOHOL DISTILLERS HANDBOOK, Righelato et al. (Anaerobic Fermentation: Alcohol Production [and Discussion]) and Richards et al. (OXYGEN CONSUMPTION AND CARBON DIOXIDE PRODUCTION DURING THE GROWTH OF YEAST).

Todd, Jr. et al. disclose synthesis of hydrogenated purified beta acid (hexahydrolupulon) and its use as a selective inhibitor of cell growth (Col. 2 lines 33-41, Col. 3 lines 7-20). In regard to claim 2,Todd, Jr. et al. disclose "[a] process for

producing hexahydrolupulone which comprises of the steps of contacting beta acids in an alkaline solution with a metal oxide, hydroxide, or salt" (Col.2 lines 33-36). In regard to claims 2 and 14, Todd, Jr. et al. disclose "the addition of hexahydrolupulone to a yeast culture to inhibit the growth of Lactobacillus therein" (Col. 3 lines 7-8). In regard to claims 2 and 14, Todd, Jr. et al. disclose "the inhibition of a Lactobacillus microorganism in the presence of yeast without inhibiting growth of the yeast by the application of a Lactobacillus-inhibiting amount of hexahydrolupulone thereto" (Col. 3 lines 9-11). In regard to claims 2 and 14, Todd, Jr. et al. disclose "the selective inhibition of one microorganism in the presence of another by the application of an amount of hexahydrolupulone which is inhibitory as to the one microorganism but not the other" (Col. 3 lines 16-19). In regard to claim 3, Todd, Jr. et al. disclose 0.2% solution of hexahydrolupulone (Example 6). In regard to claims 5, 6 and 15 Todd, Jr. et al. disclose hexahydrolupulone (hexahydrobeta acid) (Example 4). In regard to claim 8, Todd, Jr. et al. disclose that "[t]he resulting pure hexahydrolupulone is useful as a growth inhibitor in such forms as a stable alkaline solution in water" (Col. 3 lines 40-43). In regard to claim 8, Todd, Jr. et al. discloses using KOH or NaOH and adjusting pH to 10 during hexahydrolupulone synthesis (Example 5). Todd, Jr. et al. disclose that:

> Similar treatment of a 10% sugar solution, inoculated with yeast, did not inhibit fermentation. Accordingly, it is evident that the hexahydrolupulone solution may be used to selectively inhibit growth of specific cell lines, for example, the selective inhibition of Lactobacillus in the presence of yeast. Moreover, its use in inhibiting Lactobacillus infections in the brewhouse will become immediately apparent to one skilled in the brewing art. Other useful applications in fermentation processes, as well as pharmaceutical applications, will also be apparent to one skilled in the art.

> (88) Although the hexahydrolupulone may be used as a neutral solution in alcohol or the like, its preferred form is as a stable alkaline solution as described in Example 5.

In regard t o claim 9 and 20-21, Todd, Jr. et al. disclose that inhibition process was varied out at 20 degrees C (Example 6). In regard to claim 10, Todd, Jr. et al. disclose 0.2% solution of hexahydrolupulone to provide 50 ppm in the culture (Example 6).

Todd, Jr. et al. do not disclose that pH of the aqueous alkaline hop acid solution is higher than the pH of the aqueous process medium, the aqueous alkaline hop acid solution contains from about 2 to about 40 wt. % of hop acid, the aqueous process medium is a process medium in a yeast production process.

Since Todd, Jr. et al disclose that "[t]he resulting pure hexahydrolupulone is useful as a growth inhibitor in such forms as a stable alkaline solution in water", alkaline solution would inherently have high pH value due to the presence of hydroxide ions in the solution. Since Todd, Jr. et al. disclose lower concentration of hexahydrolupulone than recited and the fact that disclosed hexahydrolupulone was highly purified, it would have been obvious to vary concentration of hop acid in a hop acid alkaline solution depending on the level of acid purity. Since Todd, Jr. et al teach selective inhibition of one microorganism (bacilli generally and other bacteria) in the presence of yeast by the application of an amount of hexahydrolupulone which is inhibitory as to the one microorganism but not the yeast, it would have been obvious to employ the process as disclosed by Todd Jr. et al. in the yeast production process in order to inhibit the growth of all unwanted cells except for yeast as taught by Todd, Jr. et al.

Todd Jr. et al is silent as to the addition of hop acid solution to yeast in a yeast growing tank. As evidenced by ALCOHOL DISTILLERS HANDBOOK, "[h]ops extract is occasionally used with water for preparation of yeast mashes because it contains resins and is believed to inhibit the growth of microorganisms" (p. 57). Since Todd, Jr. et al disclose use of hexahydrolupulone to inhibit the growth of Lactobacillus in the brewhouse (alcohol production) and in other fermentation processes (Col. 8 lines 8-12), and since it was well known in the art to use hop acids (resins) extracts for preparation of yeast fermentation mashes in alcohol (ethanol) production, one of the ordinary skill in the art would have been motivated to modify disclosure of Todd, Jr. et al and to use hop acids extract in ethanol (alcohol) production at any stage of the ethanol production where inhibiting of bacteria is required. One of ordinary skill in the art would have been motivated to use hop acids solutions in production of ethanol to inhibit growth of Lactic acid bacteria, since it was well known in the art to use hop acids (resins) extracts for preparation of yeast fermentation mashes in alcohol (ethanol) production for antibacterial purposes. One of ordinary skill in the art would have been motivated to add hop acids solutions to the yeast growing tank, and then to transfer the mixture to the fermentation vessel, since Todd, Jr. et al. disclose "the addition of hexahydrolupulone to a yeast culture to inhibit the growth of Lactobacillus therein" (Col. 3 lines 7-8).

Todd Jr. et al is silent as to the aerobic conditions of yeast growth and anaerobic conditions for fermentation. Righelato et al. discloses that "Fermentation, the anaerobic catabolism of carbohydrates, proceeds by the oxidation of sugars to pyruvic acid, which process yields the cell energy and produces reduced nucleotides and a number of

products that are potentially useful to man (table 1). Ethanol is the most widely known of these, as an industrial product, made by the reductive decarboxylation of pyruvate. From each mole of hexose, 2 mol of ethanol are generated conserving over 90 % of the calorific value of the sugar in the product". Richards et al discloses consumption of oxygen during the yeast growth. Therefore, one of ordinary skill in the art would have been motivated to modify Todd and to employ conventional conditions for alcohol fermentation and yeast growth such as aerobic for yeast growth and anaerobic for fermentation.

Claims 7 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of ALCOHOL DISTILLERS HANDBOOK, Righelato et al. (Anaerobic Fermentation: Alcohol Production [and Discussion]) and Richards et al. (OXYGEN CONSUMPTION AND CARBON DIOXIDE PRODUCTION DURING THE GROWTH OF YEAST) as applied to claims 2-6, 8-11, 14-15 and 20-21 above and further in view of Simpson (Synergism Between Hop Resins and Phosphoric Acid And Its Relevance To The Acid Washing of Yeast).

Kaneda et al (Beer Absorption on a Lipid Membrane as Related to Sen Evaluation) cited as evidence as discussed below.

Todd, Jr. et al., ALCOHOL DISTILLERS HANDBOOK, Righelato et al., Richards et al. are taken as cited above.

Todd, Jr. et al. do not disclose isomerized hop acid.

Simpson discloses that hop acids present in the brewery yeast slurries have a bacterial action on lactic acid bacteria during the acid washing process (p. 405). Simpson disclose introduction into microorganisms of aqueous solution of "isomerised hop extract (ISOHOPCO2N, Pauls Hop Products, England) hopped to a level of 60° EBCBU" (p. 406). Simpson also discloses that solution contains 0-85% NaCl (p. 406). Thus Simpson discloses alkaline aqueous solution of isomerized hop acid. Simpson also discloses that alkaline aqueous solution of isomerized hop acid is maintained at 5° C (p. 406). As evidenced by Kaneda et al (Beer Absorption on a Lipid Membrane as Related to Sen Evaluation), the concentration of isomerized acids in ISOHOPCO2N product is 30%, in particular the concentration of isohumulone (isoalpha acid) is 21.6%.

Since Todd Jr. et al disclose aqueous hop acid alkaline solution as a selective inhibitor of cell growth, and Simpson discloses that hop acids have a bacterial action on lactic acid bacteria and adding aqueous isoalpha acid alkaline solution to yeast, it would have been obvious to modify disclosure of Todd et al and substitute synthesized hexahydrolupulone with commercially available aqueous isoalpha hop acid alkaline solution (ISOHOPCO2N) as a cell growth inhibitor in order to simplify the process and avoid multiple steps of hexahydrolupulone synthesis.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of ALCOHOL DISTILLERS HANDBOOK, Righelato et al. (Anaerobic Fermentation: Alcohol Production [and Discussion]) and Richards et al. (OXYGEN CONSUMPTION AND CARBON DIOXIDE PRODUCTION DURING THE GROWTH OF YEAST) and Simpson (Synergism

Between Hop Resins and Phosphoric Acid And Its Relevance To The Acid Washing of Yeast) and further in view of Todd, Jr. (US 4,002,863) hereinafter '863 Patent.

Todd, Jr. et al., ALCOHOL DISTILLERS HANDBOOK, Righelato et al., Richards et al. and Simpson are taken as cited above.

In regard to claim 12, Simpson discloses isoalpha acid extract. In regard to claim 13, Simpson discloses that alkaline aqueous solution of isomerized hop acid is maintained at 5° C (p. 406).

Todd, Jr. et al. and Simpson do not disclose steps of aqueous alkaline hop acid solution preparation as recited.

'863 patent discloses a process for isomerizing alpha acids to iso-alpha acids. '863 patent discloses "a process for transforming an alpha acid into an iso-alpha acid, involving contact of the alpha acid with an aqueous solution of a metal ion, comprising the steps of contacting an aqueous solution of the metal ion with a water-immiscible organic solvent solution of the alpha acid under conditions where the alpha acid is dissolved or remains dissolved in said organic solvent and effecting the desired isomerization in the water-immiscible organic solvent with or without prior separation of said solvent containing said alpha acid from the aqueous phase, having numerous advantages over the prior art as herein elsewhere set forth" (Col. 4 lines 10-22). '863 patent discloses "the pH of any water phase is above 8.0 and preferably 13 or below and the temperature is below 50°C" (Col. 4 lines 31-33). '863 patent discloses "metal ions are introduced into the said hop extract while the solvent is present, the mixture

held until isomerization occurs, and the solvent removed; metal ions are removed by washing the said hop extract contained in the solvent with dilute acid prior to removal of the solvent; the said mixture is held at a temperature below 50°C until isomerization occurs" (Col. 4 lines 40-47). '863 patent teaches the following advantages of the disclosed method: it eliminates the need to remove the solvent from the extract prior to isomerization; it permits continuous processing of the hops, from extraction to isomerization to solvent removal, without intermediate heating and cooling of the solvent; it permits the isomerization to be conducted at an increased rate, under conditions which eliminate the hazard of oxidation, hydrolysis, and further isomerization of the iso-alpha acids; it eliminates the necessity for carefully controlled amounts of reagents which, combined with mild conditions, makes the reaction foolproof; it greatly reduces the size and volume of equipment required to process a given quantity of hops, because the concentration of extract in the water-immiscible solvent is not critical, and may in the process of this invention be very high (Col. 10 lines 50-68).

Since Simpson discloses that hop acids have a bacterial action on lactic acid bacteria and adding aqueous isoalpha acid alkaline solution to yeast, and '863 Patent teaches a process for isomerizing alpha acids to iso-alpha acids, it would have been obvious to modify combined teachings of Todd, Jr. et al. and Simpson and employ a method of preparation of aqueous alkaline hop acid solution in order to obtain aqueous isoalpha acid alkaline solution with all the commercial advantages listed above as taught by '863 Patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VERA STULII whose telephone number is (571)272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vera Stulii/
Examiner, Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794